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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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SUBJECT: Environmental exposure characterization and assessment for the New Use of the

insecticide ZetaGard LBT (Litter Beetle Treatment) active ingredient (a.i.)

0.750% piperonyl butoxide for use on poultry litter in broiler and turkey grow-out

houses.

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The Environmental Fate and Effects Division (EFED) has conducted a screening-level environmental exposure characterization and assessment for the proposed Section 3 new product ZetaGard LBT (Litter Beetle Treatment). This product contains 0.750% piperonyl butoxide (PBO) (submission package 905152), and 0.375% Zetacypermethrin (2S) as the active ingredients. The assessment for zetacypermethrin (2S) is presented in a separate document (DP Barcode: 397296). ZetaGard LBT (Litter Beetle Treatment) is an insecticide for the control of Darkling Beetles (Alphitobius diaperinus) in poultry litter of chicken broiler and turkey grow-out houses.

A full environmental risk assessment was not performed. Results of the analysis indicate that the highest calculated outdoor use equivalent application rate is 0.14 lbs. PBO/ acre; well below the 0.5 lbs./ acre for PBO's currently registered outdoor use application rate. Highly conservative assumptions were used to calculate the outdoor equivalent application rates, which clearly demonstrate that risk potential for this proposed new use is considerably lower than use patterns already registered. This assessment also presents a methodology used to determine this conclusion.

Another important finding in this assessment is that PBO is not registered for forestry lands where poultry litter could be applied; therefore, the spatial scope of PBO application to the environment could be expanded unless labels specifically disallow application to managed forest lands. Forestry PBO outdoor equivalent application rates, however, are similar to the calculated maximum outdoor equivalent application rate calculated in this assessment.

1. SUMMARY

The Environmental Fate and Effects Division (EFED) has conducted a screening-level environmental exposure characterization and assessment for the proposed Section 3 New Use product ZetaGard LBT (Litter Beetle Treatment). The product's active ingredients (a.i.) include 0.375% Zeta-cypermethrin (2S), and the synergist compound of 0.750% piperonyl butoxide (submission package 905152). The registrant proposes to use ZetaGard inside poultry houses, in particular chicken broilers and turkeys, for the control of the Darkling Litter Beetle (Y-Tex, 2012).

1.1. Background

For the synergist piperonyl butoxide (PBO), USEPA previously completed an environmental risk assessment (USEPA, 2005), and a problem formulation (USEPA, 2010; DP Barcode D378420).

PBO is currently registered for *outdoor uses* and can be applied to the land for an array of food and grain crops (*e.g.* corn, wheat, hay) and horticultural crops (*e.g.* tomatoes, herbs, ornamentals) at the maximum application rate of 0.5 lbs a.i./ acre (USEPA, 2010; DP Barcode D378420). Conversely, PBO is also currently registered for *indoor uses* of agricultural farm structures including poultry houses at the maximum application rate of 0.56 lbs a.i./ 1,000ft² (USEPA, 2010; DP Barcode D378420). PBO, as part of the ZetaGard product, is proposed for indoor use of poultry houses at a rate of 0.01875 lbs a.i./ 1,000ft² (Y-Tex, 2012).

Pursuant to the application method described in the registrant's proposed new use label, ZetaGard is to be applied indoors of poultry houses that will enable PBO to become embedded in the poultry litter. This litter will subsequently be routinely removed from the poultry house and, in most cases (nearly 90%), be applied outdoors as a source of nutrients for agronomic crop production purposes (USDA, 2012b; USDA, 2011; MacDonald *et al.*, 2009; USDA, 2009; MacDonald, 2008; USDA, 2008; and, Moore *et al.*, 1998).

Through the National Pollution Discharge and Elimination System (NPDES) program of the Clean Water Act (CWA), USEPA regulates the land application of poultry litter from concentrated animal feeding operations (CAFO). A state approved comprehensive nutrient management plan (CNMP) is required whenever accumulated poultry litter collected from inside poultry houses of CAFO's is then applied to cropland. A CNMP balances the nutrient content in the poultry litter with the nutrient needs of the agriculture, horticulture or forestry crop where the poultry litter might be land applied (USEPA, 2012; and USEPA, 2003).

Although, the registrant proposed to apply PBO inside poultry houses below the currently registered indoor use application rate of 0.56 lbs a.i./ 1,000ft², it was not clear what amount of residual PBO would be embedded in poultry litter, and the consequential outdoor equivalent application rate.

Thus, USEPA developed a methodology that quantifies the relationship between PBO's proposed application rate for *indoor use*, and its consequential secondary *outdoor use* equivalent

application rate through land utilization of poultry litter. This methodology was used for broilers, turkey toms and turkey hens. The resultant PBO calculated outdoor equivalent application rate can then be assessed with its currently registered outdoor application rate. This assessment, in conjunction with other factors, can be used to help determine whether additional exposure analyses or risk assessments are warranted.

1.2. Methodology Overview

When the active ingredient, PBO, is intentionally applied for indoor use in accordance with the proposed label and becomes embedded in the poultry litter, USEPA adapted and developed methodologies for this proposed new use that estimate the:

- 1) Concentration of PBO in the poultry litter (lbs a.i./ ton manure); and,
- 2) Outdoor equivalent application rates (lbs a.i./ acre), when the treated poultry litter is land applied as an agronomic fertilizer.

Descriptions of computational methodologies are presented in later sections throughout this assessment.

1.3. Results

Table 1 compares PBO's currently registered outdoor use application rate to the calculated outdoor use equivalent application rates by poultry type. The highest calculated outdoor equivalent application rate for PBO is 0.14 lbs/ acre; 28% of the currently registered outdoor application rate of 0.5 lbs a.i./ acre. These calculated equivalent application rates are based on multiple conservative assumptions and fully discussed elsewhere in this assessment.

Table 1: Comparison between PBO's currently registered outdoor application rate and the calculated outdoor equivalent application rates.

Currently Registered Outdoor Use Application Rate (USEPA, 2010; DP Barcode D378420)	Calculated Outdoor Use Equivalent Application Rates			
	Chicken (broilers)	Turkey (toms)	Turkey (hens)	
	1t	os a.i./ A	1	
0.5	0.14	0.10	0.14	

Abbreviations: A = acre; a.i. = active ingredient; lbs = pounds

1.4. Recommendations

- 1) If PBO treated poultry litter is to be land applied (e.g. agronomic, horticultural, compost, or other purposes), the proposed new use product should include language that stipulates that the product should be used in accordance with a comprehensive nutrient management plan (CNMP).
- 2) Submission of degradation studies with PBO in poultry litter would reduce uncertainty in this assessment.

3) PBO does not appear to be registered in forestry; therefore; Registration Division should consider that the proposed label should be amended to preclude application of treated poultry litter to forest lands.

2. USE CHARACTERIZATION

ZetaGard is proposed to be applied to poultry litter of broilers (*i.e.* chickens raised for meat) and turkeys in grow-out houses for the control of darkling beetles (*Alphitobius diaperinus*), and other insects, such as beetles, aphids and numerous Lepidoptera (Y-Tex, 2012).

The proposed new product, ZetaGard LBT (Litter Beetle Treatment) is an insecticide containing 0.375% zeta-cypermethrin (2S), and 0.750% piperonyl butoxide (PBO). PBO acts as a synergist to zeta-cypermethrin by inhibiting the mixed function oxidase system of insects and reduces the oxidative breakdown of other pesticides (USEPA, 2010; DP Barcode D317886).

Figure 1 illustrates how broilers and turkeys are housed in large structures with floor areas ranging from 12,000 to more than 20,000 square feet. Broilers and turkeys are raised on deep bedding material (e.g. wood shavings, sand, straw, peanut shells, or other locally available material) in open-floor environments where they move freely throughout the house (USDA, 2011a; and, Stringham et al., 2005). Poultry manure¹, feathers and spilled feed accumulate in the bedding material on the facility floor and becomes litter² where it is stored in-situ (USDA, 2011a; USDA, 2008; and, USDA, 2009).

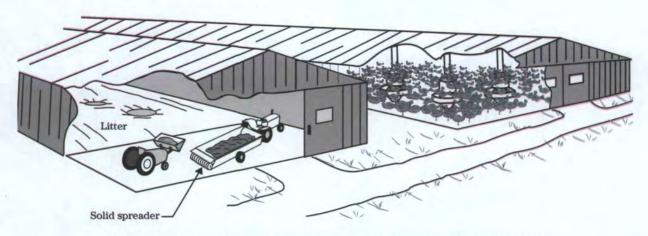


Figure 1: Illustration of litter system for Broiler and Turkey operations (USDA, 2011a).

Growers generally raise five or six broiler flocks annually for a period of about six weeks per flock, after which they are removed to market. A new flock of day-old broilers is placed in the broiler grow-out house within two to four weeks, allowing time for the grower to remove cake³, clean and disinfect the building. Complete litter removal from broiler houses varies from once to twice a year, or even once every 2 years (Ritz and Merka, 2009; USDA, 2011a; USDA, 2008; and, Stringham *et al.*, 2005).

¹ Manure refers to materials that have a high percentage of feces and urine (USDA, 2008).

² Litter is defined as the form of poultry waste that results from floor production of birds after an initial layer of a bedding material, such as wood shavings, is placed on the floor at the beginning of and perhaps during the production cycle (USDA, 2008)

³ Cake refers to the litter surface crust and wet spots resulting from spilled water and has clumped together and removed during cleaning between flocks (USDA, 2012; and, 2008).

Turkey production schedules and methods are somewhat different. Young turkeys are most often placed in brooder houses for the first six weeks of their lives, after which they are moved to the grow-out houses; where the ZetaGard LBT will be applied. Turkey hens (females) are typically grown for 12 to 17 weeks, and turkey toms (males) from to 17 to 21 weeks (USDA, 2008; and, Voris *et al.*, 1998). Facility cleaning and disinfection takes two- to four-weeks between flocks. Litter wastes are generally removed from turkey grow-out houses once a year (Stringham *et al.*, 2005).

Approximately 81% of poultry producers apply insecticides for the control of darkling beetles because they are the most serious problem to structural integrity of poultry houses (Stringham, *et al.*, 2005).

The proposed application method is with a drop style dust/ granular applicator spread on top of the bedding material along the inside of the poultry house floor adjacent to the outside walls, and under feed and water troughs where spillage often occurs creating a moist environment for insects. The registrant proposes to use ZetaGard LBT for two separate application scenarios (Y-Tex, 2012):

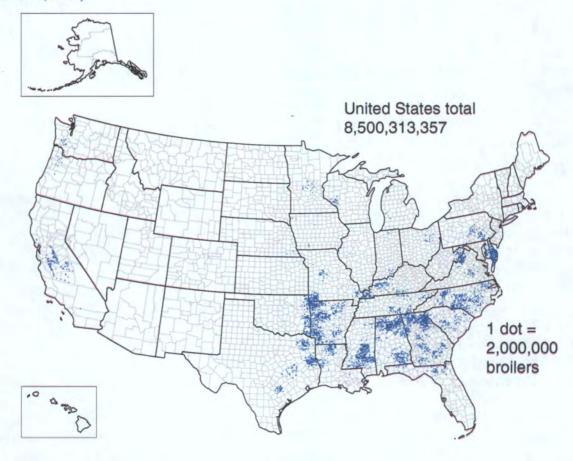
1) Before poultry (broilers and turkeys) are placed in the house, the product is to be applied not more than 50 lbs (0.375 lbs PBO a.i.) per six week period; and,

2) After poultry (primarily turkeys) are placed in the house, the product is to be applied not more than 25 lbs (0.1875 lbs PBO a.i.) per six week period.

2.1. Geographic Distribution

Figure 2 illustrates the geographic distribution and density of broiler operations in the United States. A total of 8.6 billion broilers were produced nationally in 2010, and is nearly equal to production numbers of 2002 depicted in Figure 2. The top five broiler producing states include: Georgia, Alabama, Arkansas, Mississippi and North Carolina with an estimated 4.9 billion broilers (57%) produced in 2010 (U.S. Census Bureau, 2012; and USDA, 2012a). Another estimated 534.7 million broilers (6.2%) were raised in the Delmarva Peninsula region of the east coast. Turkey production in 2010 is more diversified geographically with Minnesota, North Carolina, Missouri, Indiana, and Arkansas as the leading top five producing states (U.S. Census Bureau, 2012). Both Arkansas and North Carolina are among the top five poultry producers for broilers and turkeys. Mapped data for turkey production is not included.

Figure 2: Geographic distribution and density of broilers in the United States, 2002 (MacDonald, 2008)

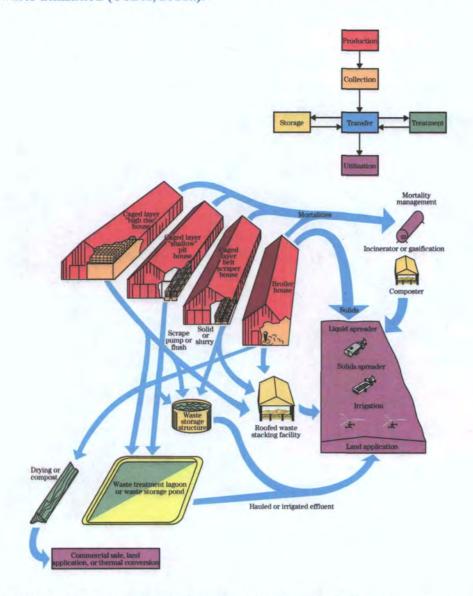


2.2. Exposure Pathways

To accurately characterize the potential environmental exposure pathways, selecting the appropriate livestock waste management system is necessary when assessing pesticides (*e.g.* PBO) intentionally applied to poultry litter. Figure 3 illustrates the various poultry litter management systems (USDA, 2011a) and identifies common exposure pathways of pesticides embedded in manure.

Broiler and turkey farmers use the dry litter management system (USDA, 2011a). This system is depicted in Figure 3 as the "solids" leaving the "broiler (or turkey) house" and land applied in the "solids spreader", temporarily stored covered on-site, or composted. The benefits of dry litter management systems are primarily for the poultry's health, reduced disease, welfare and production performance (FASS, 2010). Additionally, operational costs for storage, transportation and application of dry litter are typically lower than liquefied manure waste management systems (USDA, 2011a).

Figure 3: Illustration identifying various potential PBO exposure pathways through poultry litter waste utilization (USDA, 2011a).



The resultant poultry litter is utilized in an array of products such as: an agronomic crop fertilizer; feed ingredient for ruminant livestock (*i.e.* cattle); a source for biogas energy; and, when composted, biologically stable, odor free and marketable product for horticultural applications (*e.g.* vegetables, fruit and garden nurseries), golf courses, and sometimes even reused for bedding material (USDA, 2009; USDA, 1992; and, Moore *et al.*, 1998).

Approximately forty percent of broiler production, and 45 percent of total poultry production, occurs on farms with no cropland acreage (USDA, 2009). In a 2006 survey of broiler farms, nearly 40% of all litter was applied to the operator's crop fields while the remaining 60% was transported off-site⁴ (USDA, 2008). The "vast majority" of poultry litter, whether applied

⁴ Quantitative data characterizing the use of broiler litter transported off-site was not provided in the referenced

on or off-site, is spread as a fertilizer to cropland, or pasture and hay land (MacDonald *et al.*, 2009; USDA, 2009; USDA 2008; and, Moore *et al.*, 1998). Thus, the primary route of environmental exposure to residual PBO in poultry litter is through the land application to agricultural crop, pasture fields and even forest lands. Figure 4 depicts an example of how dry poultry litter is spread on cropland; wheat stubble (Poultry Hub, 2012).

Figure 4: Example of dry poultry litter spread on wheat stubble with surface application without incorporation (Poultry Hub, 2012).



2.3. Crops Receiving Poultry Litter

Used poultry litter was applied to approximately 896,000 cropland acres in 2006 (MacDonald *et al.*, 2009). Table 2 itemizes the top four commodity crop groups that received the litter include corn (52.7%), cotton (25.4%), soybeans (14.7%), and peanuts (4.9). The remaining 2.3% of commodity-type crops receiving poultry litter include barley, oats, sorghum and wheat. Poultry litter was applied to more than half of the peanut and cotton operations that use litter for fertilizer (MacDonald *et al.*, 2009). All eight crops are currently registered for PBO at the maximum application rate of 0.5 lbs/ acre (USEPA, 2012; DP Barcode D317886).

Specific data for horticultural crops receiving poultry litter was not identified. Based on 2006 broiler data, an estimated 8.5 billion broilers would have produced 11.9 million tons_(dw)

USDA, 2008 report. Other USDA documents, however, provide qualitative assertions that the "vast majority" of poultry litter is used for agronomic fertilizer applications (USDA, 2009; and, USDA 2008).

manure (MacDonald *et al.*, 2009). Thus, approximately 1.2 million tons_(dw) manure⁵ could have been available for compost and other uses to which could be applied to horticultural crops.

Table 2: Agricultural crops receiving poultry litter by acre, and crops grown outdoors currently registered for PBO application (USEPA, 2010; DP Barcode D317886; and, MacDonald, 2009)

Crop Group	Crop Type (Outdoor Growing	Acres Receiving Poultry Litter	Currently Registered PBO Outdoor Maximum Application Rates ¹⁾		
	Crops)	(x 1,000)	lbs/ A	lbs/ 1,000ft ²	
16	Corn	472	0.5	0.012	
Miscellaneous Commodities	Cotton	228	0.5	0.012	
6	Soybeans	132	0.5	0.012	
6	Peanuts	44	0.5	0.012	
17	Bermuda grass	NR	0.5	0.012	
-	Forests	NR			
1, 2, 3, 4, 5, 6, 7, 8, 9	Vegetables	NR	0.5	0.012	
10, 11, 12, 13, 14, Fruits		NR	0.5	0.012	
19	Herbs and Spices	NR	0.5	0.012	

Abbreviations: A = acre; a.i. = active ingredient; lbs =pounds; NR = not reported; -- = not included

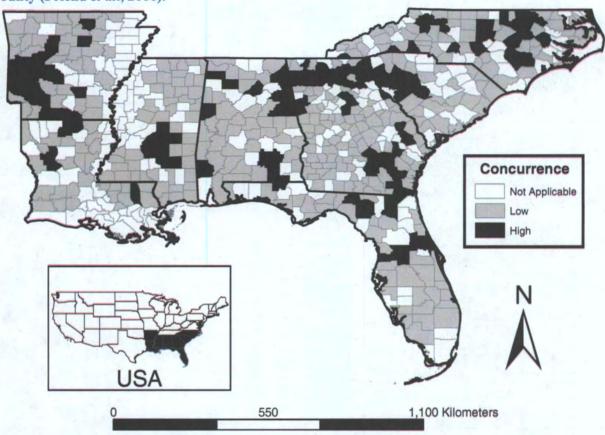
Notes:

1) Single application event with a minimum 10-day application interval.

It is important to note that PBO is not, however, currently registered for use on land application to forest lands. Thus, there is potential for residual PBO in poultry litter to be applied to forest lands where it is not currently registered. Because of concerns for crop and pasture lands becoming saturated with nitrogen and phosphorus from repeated applications of poultry litter, forest lands have recently been researched and recommended as an alternative land application site (Friend *et al.*, 2006). Published research has examined poultry litter land application rates as high as 16 tons of per acre on forest lands (Beem *et al.*, 2009; Friend *et al.*, 2006; Dickens *et al.*, 2003a; and, Dickens *et al.*, 2003b). Figure 5 illustrates the concurrence of poultry production and pine forests in the southeast where poultry litter is likely to be applied (Friend *et al.*, 2006).

⁵ This mass of manure (i.e. not litter) does not include additional bedding material that will increase the total mass and volume.

Figure 5: Concurrence of poultry production and the distribution of southern pine forests, by county (Friend *et al.*, 2006).



3. EXPOSURE CHARACTERIZATION

Detailed environmental fate and transport characteristics have been documented in PBO's environmental risk assessment (USEPA, 2005), and problem formulation (USEPA, 2010; DP Barcode: D378420). A summary of reported fate properties for PBO include: no evidence of degradation by hydrolysis; calculated vapor pressure of 5 x 10⁻¹³ torr @ 25°C; and, an aerobic soil metabolism half-life of 14-days in sandy loam soils. Studies of degradation rates of PBO in poultry litter were not identified (USEPA, 2010; DP Barcode D378420).

USEPA adapted and developed two computational methodologies that quantify the relationship between PBO's proposed application rate for *indoor use*, its residual concentration in poultry litter, and consequential secondary *outdoor use* equivalent application rate through the cropland utilization of poultry litter. The resultant PBO outdoor equivalent application rate was then compared to its currently registered outdoor application rate to help characterize PBO exposure in the environment, and determine if further exposure risk assessments are warranted. The methods include calculating:

- 1) Concentration of PBO residues in poultry litter (lbs a.i./ ton litter); and,
- 2) PBO outdoor equivalent application rates (lbs/ acre).

3.1. Concentration of PBO residues in Poultry Litter

Residues of PBO in poultry litter were estimated by quantifying the amount of the active ingredient applied, bedding material used, and poultry manure produced per poultry flock. Considerable variability and uncertainties remain, however, and conservative assumptions were used in all appropriate calculations. Methodologies and values used in this assessment were derived from state and national publications, and professional engineering society standards. Of particular note, these methods and values are for planning and assessment purposes only and results should not be interpreted for site specific conditions (USDA, 2008; ASAE, 2005; and, Lorimor *et al.*, 2000).

3.2. Methodology

Active ingredient

For the three types of poultry for which ZetaGard will be applied, Table 3 summarizes the cumulative mass of PBO per application event. Maximum PBO application rates and frequency by poultry type were used in the analysis pursuant to the registrant's proposed new use label (Y-Tex, 2012), and include the following assumptions:

- 1) Broilers:
 - a. 0.375 lbs a.i. per 6-week interval
- 2) Turkeys:
 - a. 0.375 lbs a.i. applied at the initial 6-week period, followed by
 - b. 0.1875 lbs a.i. in subsequent 6-week intervals
- 3) There are 6 separate broiler flocks and 6 applications of bedding material between complete litter removal events.
- 4) There are 3 separate turkey flocks with 9 total applications of bedding material

between complete litter removal events.

- 5) Degradation of PBO is assumed not to occur in the poultry litter; and,
- 6) Homogeneity of PBO in the poultry litter; and,
- Pesticide application events occur concurrently with the bedding material applications.

The following equations were used to calculate the cumulative⁶ mass of active ingredient (PBO) applied between complete litter-removal events for broilers and turkeys:

Equation 1: Broilers

$$a.i._{cumulative} = a.i._{i} + [(a.i._{i})(n-1)]$$

where,

a. i.cumulative = cumulative mass of active ingredient (lbs)

 $a.i._i = \text{mass of initial application of active ingredient (lbs)}$

n =mass of additional applications of active ingredient (lbs)

Equation 2: Turkeys

$$a.i._{cumulative} = a.i._{i} + \left[\left(\frac{a.i.}{2} \right) (n-1) \right]$$

where,

a. i.cumulative = cumulative mass of active ingredient (lbs)

 $a.i._i = \text{mass of initial application of active ingredient (lbs)}$

n =mass of additional applications of active ingredient (lbs)

Table 3: Cumulative mass by application event and poultry type.

Active Ingredient (PBO)	Application Events									
	1	2	3	4	5	6	7	8	9	
Broilers (lbs a.i.)	0.0375	0.75	1.125	1.5	1.875	2.25	NA	NA	NA	
Turkey Toms (lbs a.i.)	0.375	0.5625	0.75	1.125	1.3125	1.5	1.875	2.0625	2.25	
Turkey Hens (lbs a.i.)	0.375	0.5625	0.75	1.125	1.3125	1.5	1.875	2.0625	2.25	

Abbreviations: a.i. = active ingredient; NA = not applicable

⁶ Cumulative in this analysis refers to the total mass accumulated between complete house clean-out events. Poultry litter is stored in-situ between complete removal events (USDA, 2011; and USDA, 2008).

Bedding Material

Poultry producers use a range of bedding material (*e.g.* wood shavings, sand, straw, peanut shells, or other locally available material) based on availability, costs and performance properties (USDA, 2008). Producers usually replace the bedding material after three to six flocks, or once or twice a year (USDA, 2011; and, USDA, 2008).

Table 4 summarizes the cumulative amount of bedding material per application event, and between complete litter removal events. The quantity of bedding material used varies by type, flock and operational management of the facility. The following conservative assumptions and references were used to estimate the quantity of bedding material and include:

- 1) An initial quantity of 3 to 4 inches, or 10 tons of bedding material is applied at the beginning of the poultry (*i.e.* flock) production period (USDA, 2008);
- 2) Bedding material does not add nutrients, but increases the volume and mass of the resultant poultry litter (USDA, 2008);
- 3) The quantity of feed spilled or not consumed by poultry and incorporated into the litter is not included in the calculations;
- 4) For broilers, an additional 1 to 2 inches (5 tons equivalent) of bedding material are applied at the beginning of subsequent flocks without complete litter removal of the poultry house (USDA, 2008);
- 5) For turkeys, an additional 1 to 2 inches (5 tons equivalent) of bedding material cooccur every six weeks with the additional half-rate of PBO applications, and without complete litter removal from the poultry house;
- 6) Degradation or volatilization of the bedding material is assumed to be stable;
- Complete litter removal events occur about once-per-year, or for the number of poultry flocks between clean-out events (USDA, 2011; and USDA, 2008):
 - a. Broilers: 6
 - b. Turkeys: 3; and,
- 8) Operational management of bedding material is assumed similar between broiler and turkey production operations.

The following equations were used to quantify the cumulative mass of bedding material for broilers and turkeys:

Equation 3: Broilers

$$BM_{cumulative} = BM_i + \left[\left(\frac{BM_i}{2} \right) + (n-1) \right]$$

where.

 $BM_{cumulative}$ = cumulative mass of bedding material (tons)

 BM_i = Initial mass of bedding material (10 tons)

 $\left[\left(\frac{BM_i}{2}\right) + (n-1)\right]$ = Additional mass of bedding material (5 tons)

$$BM_{cumulative} = BM_i + \left[\left(\frac{BM_i}{2} \right) + (n-1) \right]$$

where.

 $BM_{cumulative}$ = cumulative mass of bedding material (tons)

 BM_i = initial mass of bedding material (10 tons)

$$\left[\left(\frac{BM_i}{2}\right) + (n-1)\right]$$
 = Additional mass of bedding material (5 tons)

Table 4: Cumulative mass of bedding material between complete poultry litter clean-out events.

				App	olication Ev	rents			
Bedding Material	1	2	3	4	5	6	7	8	9
Application Mass (tons)	10	5	5	5	5	5	5	5	5
Cumulative Mass (tons)	10	15	20	25	30	35	40	45	50

Abbreviations: tons = 2,000 pounds

A total of 35 tons of bedding material were estimated to be applied to the poultry house floor for 6 broiler flocks before the complete litter removal event occurs. Whereas, only 3 flocks of turkeys accumulated 50 tons of bedding material for the annual complete litter removal event.

Poultry Manure

Although characteristics of poultry manure vary less than other livestock (USDA, 2008), the quantity and nutrient content of manure produced can vary as much as ± 30% depending on poultry type, flock density, mortality rates, feed quality and amendments, environmental conditions, among other factors (USDA, 2012; USDA, 2008; ASAE, 2005; and, Lorimor *et al.*, 2000). Manure production rates were derived from a nutrient mass balance perspective that assumes feed intake minus animal retention equals manure excretion (USDA, 2008; and ASAE, 2005). Instead of reporting a range (± 30%) manure production rates in this analysis, the ASAE⁷ published manure production rates (ASAE, 2005) were used since conservative assumptions were throughout other calculations of the analysis.

Table 5 summarizes the quantity of manure produced per flock for the three types of poultry. The following assumptions, and corresponding references, were used in the calculations:

- 1) Pursuant to the registrant's proposed label, the treatment area of the poultry facility house is 20,000 ft² (Y-Tex, 2012);
- 2) Flock densities vary by poultry type, environmental conditions of the poultry house

⁷ ASAE: American Society of Agricultural Engineers.

and facility management (FASS, 2010; and, Voris et al., 1998):

- a. Broiler density is 1.0/ft²;
- b. Turkey tom density is $0.286/ \text{ ft}^2 (1/3.5 \text{ ft}^2)$;
- c. Turkey hen density is 0.4/ ft² (1/2.5 ft²); and,
- d. Flock densities refer to the finished animals.
- 3) Manure production rates vary by poultry type, and production duration (USDA, 2009 and 2008; ASAE, 2005; and, Lorimor *et al.*, 2000):
 - a. Broilers: 2.8 lbs manure_(dw)⁸/ broiler/ 48-days;
 - b. Turkey (toms): 20 lbs manure(dw)/ tom/ 133-days; and,
 - c. Turkey (hens): 9.8 lbs manure_(dw)/ hen/ 105-days
- 4) Typical mortality rates vary by poultry type (USDA, 2009):
 - a. Broilers 5%;
 - b. Turkey toms 9%; and,
 - c. Turkey hens 6%.
 - d. Poultry carcasses were not included in the mass of accumulated litter because some operations may choose incineration or other disposal method instead of composting the poultry mortality; and,
 - e. Producers include additional juvenile poultry at the beginning of the flock production period to account for population mortalities during production.
- 5) The manure represents the average dry weight (dw) mass to account for degradation, evaporation and volatilization, or 25% of the "as-excreted" mass of manure and urine for both broilers and turkeys (USDA, 2008; ASAE, 2005; and, Lorimor, et al., 2000).
- 6) No adjustments were included for feed quality, supplements, or amendments such as phytase, an enzyme that helps birds utilize more of the indigestible phosphorus (USDA, 2011).
- 7) Poultry house environmental conditions (e.g. lighting, temperature, humidity, etc.) were assumed appropriately managed.

For each poultry type, total manure production per flock was calculated using the following equation:

Equation 5:

Total manure $(tons_{(dw)}) = \underline{(finished animal) \times (lbs manure_{(dw)}/ finished animal)}}{(ton/2,000 lbs)}$

⁸ dw = dry weight basis

Table 5: Total manure production per flock and poultry type.

Parameter	Reference(s)	Broiler	Turkey (Tom)	Turkey (Hen)
Finished animal ¹⁾ (f.a./ flock)	Y-Tex, 2012	20,000	5,714	8,000
Manure Production Rates (lbs _(dw) / f.a./ flock)	ASAE, 2005	2.8	20	9.8
Total Manure (tons _(dw) / flock)	NA	28.0	57.1	39.2

Abbreviations: dw = dry weight; f.a. = finished animal; lbs = pounds; % = percent

Notes:

 Finished animals per flock represents finished number of birds after considerations for mortality rates of 5% for broilers, 9% for turkey toms, and 6% for turkey hens (USDA, 2009).

Residual PBO Concentration

Table 6 summarizes the calculated residual concentration of PBO embedded in the poultry litter, for broiler chickens, turkey toms and hens. The table also includes the cumulative poultry flocks' mass of PBO residue, manure and litter by poultry type. The following equations were used to estimate the residual concentration of PBO in the cumulative poultry litter:

The following equations were used to estimate the PBO residual concentration in the cumulative poultry litter for broilers and turkeys:

Equation 6:

Cumulative bedding material (tons) = (bedding material/flock) x (flocks per year)

where.

Bedding material = data from table 4

Equation 7:

Cumulative manure (tons) = (manure/ flock) x (flocks per year)

where,

Manure = data from table 5

Equation 8:

Cumulative litter (tons) = (cumulative bedding material) + (cumulative manure)

Equation 9:

Residual concentration (lbs a.i./ ton litter) = (cumulative PBO) / (cumulative litter)

where.

Cumulative PBO = active ingredient (lbs)

Cumulative litter = poultry litter (tons)

Table 6: Residual concentration of PBO in litter by poultry type.

	Reference(s)	Broiler	Turkey (Toms)	Turkey (Hens)
Cumulative Flocks ¹⁾	USDA, 2008; and, Voris et al., 1998	6	3	3
Cumulative PBO (lbs a.i.)	Table 3	2.25	2.25	2.25
Cumulative Bedding Material (tons)	Table 4; and, Equation 6	35.0	50.0	50.0
Cumulative Manure ²⁾ (tons _(dw))	Table 5; and, Equation 7	168	171.3	117.6
Cumulative Litter (tons)	Equation 8	203	221.3	167.6
Residual Concentration (lbs a.i./ ton litter)	Equation 9	0.011	0.010	0.013

Abbreviations: a.i. = active ingredient; dw = dry weight; lbs = pounds

Notes:

 Cumulative flocks represent the number of flocks between complete litter removal and whole house clean-out events; which typically occur once per year (USDA, 2011; and, USDA, 2008).

 Cumulative manure production represents the total mass, on a dry weight basis, of manure produced between litter removal events.

Results indicate that the estimated residual concentrations of PBO vary as much as 30%, 0.010 lbs a.i./ ton and 0.013 lbs a.i./ ton for turkey toms and hens, respectively. Turkey hens have the highest residual concentration of PBO, but have the lowest amount of cumulative poultry litter to dispose. Conversely, turkey toms produce the largest amount of cumulative litter, which effectively dilutes the concentration PBO in the poultry litter.

3.3. PBO Outdoor Use Equivalent Application Rates

There is no regulatory mechanism that assures the PBO embedded poultry litter will be land applied at less than the currently registered maximum outdoor application rate. Poultry litter land application rates were used to calculate PBO's outdoor use equivalent application rate.

USEPA adapted elements of the comprehensive nutrient management planning (CNMP) process to estimate poultry litter land application rates. A nutrient management plan balances the nutrients (*e.g.* nitrogen and phosphorus) contained in poultry litter with the needs of the crop where the poultry litter is applied.

Two computational strategies can be used for nutrient management planning to calculate poultry litter utilization rates for agronomic land applications. These include the management for (USDA, 1994; and USDA, 1992):

- 1) Maximum application rate for poultry litter (nitrogen-based); and,
- 2) Maximum nutrient efficiency (phosphorus-based).

Many states (e.g. Chesapeake Bay watershed) limit the amount of livestock manure and litter application rates based on the phosphorus needs of the agricultural crop. The continuous application of poultry litter when based on nitrogen-based needs of the crop will likely result in a build up phosphorus and potassium in the soil, and subsequently lead to animal health and water quality concerns (USDA, 1994; USDA, 1992; and EPA, 2012). However, recommendations for nitrogen-based poultry litter applications do exist, and thus the maximum litter application rate (tons/ acre) will also yield higher PBO application rates (lbs a.i./ acre). USEPA assessed the nitrogen-based strategy (i.e. Strategy 1) to estimate the most conservative PBO outdoor equivalent application rate as litter application rates based on phosphorus will be less than those based on nitrogen.

3.4. Methodology Overview

The following steps describe the methodology that was adapted from published USDA waste utilization and USEPA manure land application protocols for concentrated animal feeding operations. This adapted method is used to quantify the nutrient content of the poultry litter and subsequent litter land application rates (USEPA, 2012; USDA, 1994; and, USDA 1992):

- 1) Estimate nutrients in the excreted manure;
- 2) Add nutrients in wastewater, dropped feed, and added bedding;
- 3) Subtract nutrients lost during storage;
- 4) Determine the plant available nutrients contained in the manure;
- 5) Determine the nutrient required by the crop and soil the produce the yield goal;
- 6) Estimate nitrogen losses that can occur when manure is applied to the soils;
- 7) Select nutrient for calculation of manure application rates;
- Compute the acres on which manure can be applied to use the nutrients available; and.
- 9) Determine the manure application rates.

To account for the residual PBO in the poultry litter, the following additional steps

include:

- 1) Add in PBO to the manure application rates;
- 2) Compare with the Maximum Application Rate

Strategy 1: Management for maximum application rate of poultry litter

The management for maximum application rate of poultry litter occurs when the litter rate is calculated to meet the nitrogen need of the crop. Although this maximizes the application rate of manure it will result in an over application of phosphorus and potassium for the crop's nutrient needs. This will ultimately lead to an undesirable accumulation of plant nutrients in the soil and possibly lead to animal health and water quality concerns (USDA, 1992). Because of its chemical nature, nitrogen is more difficult to manage in manure than other nutrients (USDA, 2001a).

Table 7 summarizes the cumulative mass of retained nitrogen in the litter for the three types of poultry. The following conservative assumptions, and corresponding references, were used in the calculations:

- 1) Finished animals (Table 5):
- 2) Elemental nitrogen content varies by poultry type (USDA, 2008; and, ASAE, 2005):
 - a. Broiler is 0.12 lbs / finished animal;
 - b. Turkey tom is 1.2 lbs / finished animal; and,
 - c. Turkey hen is 0.57 lbs / finished animal.
- 3) Cumulative flocks between complete litter removal events (Table 6):
 - a. Broilers: 6 (USDA, 2008);
 - b. Turkey (toms): 3 (Voris et al., 1998); and,
 - c. Turkey (hens): 3 (Voris et al., 1998).
- 4) Nitrogen from wastewater and spilled feed is assumed to be zero.
- 5) Retained nitrogen after storage is 55% (USDA, 1992);

The following equations were used to calculate the cumulative mass of retained nitrogen in poultry litter for broilers and turkeys:

Equation 11:

Cumulative nitrogen in manure = (f.a./ flock) x (lbs N f.a.) x (cumulative flocks)

where,

f.a./ flock = number of finished animals per flock

lbs N/ f.a. = pounds of nitrogen per finished animal

Cumulative flocks = number of flocks between complete litter removal events

⁹ Retained nitrogen is the quantity of nitrogen remaining in poultry litter after losses due to volatilization during insitu storage (USDA, 1992).

Equation 12:

Cumulative residual nitrogen (lbs) = cumulative nitrogen (lbs) $\times 0.55$

where,

0.55 = Percentage of nitrogen retained after storage (USDA, 1992)

Equation 13:

lbs N/ ton litter = Retained nitrogen (lbs) / Litter (tons)

where,

Retained nitrogen (lbs) = quantity of nitrogen after storage (Table 7)

Litter (tons) = cumulative litter (Table 4)

Table 7: Calculated nitrogen content in poultry litter by poultry type.

Parameter	STEP	Reference(s)	Broiler	Turkey (Tom)	Turkey (Hen)
Finished animals (f.a. /flock)	1	Table 3	20,000	5,715	8,000
Excreted Nitrogen Content per Finished Animal (lbs/ f.a.)	1	USDA, 2008; ASAE, 2005	0.12	1.2	0.57
Cumulative Flocks	1	USDA, 2008; Voris <i>et al.</i> , 1998	6	3	3
Cumulative As-Excreted Nitrogen (lbs)	1	Equation 11	14,400	20,574	13,680
Nitrogen Spilled Feed (lbs)	2	USDA, 1992	0	0	0
Cumulative Retained Nitrogen (55%) (lbs)	- 3	USDA, 1992; Equation 12; and,	7,920	11,316	7,524
(lbs N/ ton litter) ²⁾	3	Equation 13	39.0	51.1	44.9

Abbreviations: A = acre; a.i. = active ingredient; dw = dry weight; f.a. = finished animal; lbs = pounds; ton = 2,000 lbs

The estimated retained nitrogen in poultry litter represents 55% of the "as-excreted" nutrient content in manure after storage in the poultry house. Turkey toms have the highest cumulative amount of retained nitrogen, and similarly on a per ton litter basis.

Table 8 presents the calculated poultry litter land application rates (tons/ acre) by type of poultry. These rates are based on balancing the needs of the crop and results of the calculated nitrogen content of the poultry litter. The following conservative assumptions, and corresponding references, were used in the calculations:

- 1) Non-irrigated corn was the selected agronomic crop with a nitrogen application rate of 220 lbs N/ acre (Vitosch *et al.*, 1995); and,
- 2) For plant available nitrogen (PAN) in the first year, mineralization rates are 90% (USDA, 1992);
- 3) Nitrogen losses of 50% were selected because of application method were attributed to dry weather without incorporation (USDA, 1992).

The following equations were used to calculate the poultry litter land application rates for broilers and turkeys:

Equation 14:

Plant available nitrogen (lbs) = retained nitrogen (lbs) x 0.90

where.

Retained nitrogen by poultry type was from Table 7

0.90 = Nitrogen mineralization rates after storage (USDA, 1992)

Equation 15:

Nitrogen Application Losses (lbs) = plant available nitrogen (lbs) x 0.5

where.

0.5 = Nitrogen remaining after losses during application (USDA, 1992)

Equation 16:

Acres Needed = Plant available nitrogen (lbs N) / Nitrogen Application Rate (lbs N/ acre)

where,

220 = Nitrogen application rates for non-irrigated corn (Vitosch *et al.*, 1995)

Equation 17:

Litter Application Rate = Cumulative Litter / (Acres Needed)

Table 8: Nitrogen-based outdoor litter land application rates by poultry type.

Parameter	STEP	Reference(s)	Broiler	Turkey (Tom)	Turkey (Hen)
Plant Available Nitrogen ¹⁾ (lbs N)	4	USDA, 1992; and, Equation 14	7,128	10,184	6,772
Crop Nitrogen Requirements ²⁾ (lbs PAN/ A)	5	Vitosch, et al., 1995	220	220	220
Nitrogen Application Losses (50%) Lbs)	6	USDA, 1992; and, Equation 15	3,564	5,092	3,386
Acres Needed	83)	Equation 16	16.2	23.1	15.4
Cumulative Litter (tons)	NA	Table 4	203	221.3	167.6
Poultry Litter Land Application Rate (tons/ A)	9	Equation 17	12.5	9.6	10.9

Abbreviations: A = acre; a.i. = active ingredient; lbs = pounds;

Notes:

- Plant available nitrogen (PAN) is the nitrogen that is mineralized to the inorganic form available for uptake by the crop. USDA estimates 90% of nitrogen in poultry litter is PAN during the first year of application (USDA, 1992; and, USDA 2001a).
- Crop nitrogen requirements represent the highest nitrogen recommendations for non-irrigated corn (Vitosch, et al., 1995).
- 3) Step 7 is the USDA process refers to the specific nutrient for calculation of manure application rates. In this table, nitrogen has been selected, and thus Step 7 has not been included in the table.

When poultry litter is land applied to meet nitrogen needs for corn production, Table 9 summarizes the calculated outdoor equivalent application rates for PBO embedded in that litter. The following assumptions, and corresponding references, were used in the calculations:

- 4) Finished animals: 20,000 ft² (Y-Tex, 2012);
- 5) Nitrogen content varies by poultry type (USDA, 2008; and, ASAE, 2005):
 - a. Broiler is 0.12 lbs / finished animal:
 - b. Turkey tom is 1.2 lbs / finished animal; and,
 - c. Turkey hen is 0.57 lbs / finished animal.
- 6) Number of flocks between clean-out events (USDA, 1992):
 - a. Broilers: 6 (USDA, 2009);
 - b. Turkey (toms): 3 (Voris et al., 1998); and,
 - c. Turkey (hens): 3 (Voris et al., 1998).
- 7) Nitrogen from wastewater and spilled feed is assumed to be zero.
- 8) Residual nitrogen is 55% (USDA, 1992); and,
- 9) Mineralization rates are 90% (USDA, 1992).

The following equation was used to calculate the PBO outdoor equivalent application rates for the three types of poultry analyzed in this assessment.

Equation 18:

Outdoor Equivalent Application Rate = $(tons_{litter}/A) \times (lbs a.i./ton_{litter})$

where,

 $tons_{litter}$ / A = poultry litter application rate (Table 9)

lbs a.i./ ton_{litter}. = amount of residual PBO embedded in the poultry litter (Table 6)

Table 9: Nitrogen-based PBO calculated outdoor equivalent application rates.

Parameter	STEP	Reference(s)	Broiler	Turkey (Tom)	Turkey (Hen)
Litter Application Rate (tons/ acre)	EPA	Table 9	12.5	9.6	10.9
Residual PBO (lbs a.i./ ton _{litter})	EPA	Table 6	0.011	0.010	0.013
Outdoor Equivalent Application Rate (Lbs a.i./ Acre)	EPA	NA	0.14	0.1	0.14

Abbreviations: A = acre; a.i. = active ingredient; dw = dry weight; lbs = pounds; NA= not applicable

The PBO outdoor equivalent application rates for nitrogen-based litter application rates range from 0.1 to 0.14 lbs a.i./ acre, well below the 0.5 lbs a.i./ acre of the USEPA registered label. A number of conservative assumptions were included in the calculations. Therefore, risk to non-target wildlife is considered to be minimal compared with currently registered uses of PBO.

4. EXPOSURE ASSESSMENT

Results of the computational analyses in the PBO exposure characterization are used in the exposure assessment. Table 10 presents poultry litter's maximum application rates while attaining PBO's outdoor use current registration limit of 0.5 lbs ai./ acre (USEPA, 2010; DP Barcode D317886). The following equation was used to calculate the maximum litter application rates for each of the three types of poultry.

Equation 19:

tons litter/ A = (lbs a.i./ A) / (lbs a.i./ tons litter)

where,

tons litter/ A = mass of litter applied per acre (tons)

lbs a.i./ A = pounds of active ingredient per acre

lbs a.i./ tons litter = pounds of active ingredient per ton of litter

Table 10: Maximum potential poultry litter application rates by poultry type.

Poultry Type	PBO's Currently Registered Maximum Outdoor Application Rate ¹⁾ (lbs a.i./ A)	Estimated PBO Residual Concentration in Poultry Litter (lbs a.i./ ton)	Poultry Litter Calculated Maximum Land Application Rates (tons/ A)
Broilers	0.5	0.011	45.5
Turkey (toms)	0.5	0.010	50.0
Turkey (hens)	0.5	0.013	38.5

Abbreviations: A = acre; a.i. = active ingredient; lbs = pounds; -- = not reported; ton = 2,000 lbs

Notes:

1) Single application event with a minimum 10-day application interval.

For PBO's currently registered maximum single-event outdoor application rate, the calculated mass of poultry litter that could be applied indicates relatively high poultry litter application rates. Results of a nationwide survey of poultry producers in 2006 revealed that the aggregate average is only 5 tons poultry litter applied per acre (MacDonald, 2008).

Results in the exposure characterization section indicate that the agricultural commodity corn is concurrently registered for PBO outdoor use, and likely to receive poultry litter as a fertilizer amendment. Also, corn has, in some states, recommended nitrogen application rates of 220 lbs N/ acre. It was calculated that this is equivalent to 12.5 tons litter/ acre from broiler litter. Thus, when poultry litter application rates are less than 38.5 tons/ acre, or nitrogen application rates are similarly less than 220 lbs N/ acre, the potential for PBO to exceed the outdoor use currently registered application rate of 0.5 lbs a.i./ acre in not likely to occur.

Other crops where PBO is concurrently registered for outdoor use, and likely to receive poultry litter to meet fertilization needs have been summarized in Table 2 (page 11). Typical nitrogen application rates for cotton are about 140 lbs/ acre. Bermuda grass has nitrogen application rates of 400 lbs/ acre. However, nitrogen applications to Bermuda grass typically are split among 2 to 3 application events per year; which would result in application rates less than 200 lbs/ acre (Gaskin *et al.*, 2010; Hanson *et.al.*, 2000). Recommended forest application rates are also 200 lbs N/ acre and would be at similar single-event PBO application rates as corn.

Soybean and peanuts are also significant recipients of poultry litter; especially in the south (MacDonald *et al.*, 2009). However, these crops produce their own nitrogen and thus receive litter application rates based on phosphorus, or other nutrient needs. At maximum application rates listed for corn, the risk of PBO embedded in litter exceeding the registered application rate of 0.5 lbs/ acre is also unlikely.

Horticultural crops where PBO is concurrently registered for outdoor use and likely to receive poultry litter for nutrient needs were not quantitatively assessed. This could be an emerging issue, especially in the Delmarva Peninsula as poultry farmers seek cost-effective methods to utilize the waste litter.

As previously discussed in the use characterization section, PBO is not registered for use on land application to forest lands (USEPA, 2010; DP Barcode D378420). There is potential for residual PBO in poultry litter to be applied to forest lands where it is not currently registered.

5. UNCERTAINTIES

Uncertainties attributed to PBO's physiochemical properties, ecological effects and synergistic effects are presented in the problem formulation (USEPA, 2010; DP Barcode D317886).

For PBO intentionally applied to livestock manure, considerable uncertainties remain for quantitation of PBO embedded in the poultry litter, and subsequent litter utilization. To address these uncertainties, conservative assumptions (*i.e.* data, equations and methodologies) were derived from published state, national and agricultural professional engineering standards.

Overall, EFED is confident in the conclusions presented in this assessment. The resulting calculated application rates presented in this assessment are thought to be conservative primarily because the calculations do not include any degradation or dissipation of PBO in the poultry litter prior to application to land. PBO has been shown to degrade relatively rapid in aerobic soils, which is used as a surrogate in this case for degradation in poultry litter (T1/2 of approximately 14 days). Given that PBO embedded in litter is typically land applied outdoors weeks to months after it is has been applied inside poultry houses, degradation is likely to occur prior to application to land.

The following summarize identified uncertainties where conservative assumptions were used throughout this assessment:

- 1) Type, quantity and management of the bedding material;
- 2) Density of the poultry flock;
- 3) Poultry mortality rates;
- 4) Quantity of poultry manure produced per flock;
- 5) Quantity of feed spilled or not consumed by poultry but added to litter;
- 6) Degradation rates of PBO in poultry litter;
- 7) Homogeneity of PBO in poultry litter;
- 8) Management of poultry litter removal;
- 9) Nutrient content of poultry litter;
- 10) Poultry litter land application rates;
- 11) Composted poultry litter; and,
- 12) Horticultural product applications (e.g. vegetables, fruits, ornamentals, etc.)

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